MAR 1 4 2014

K131796

Links Medical Products Inc.

510(k) SUMMARY

Submitted by:

Owner's Name:	Links Medical Products, Inc.
Address:	9247 Research Drive Irvine, CA 92618
Contact:	Tom Buckley, Chief Executive Officer
Telephone:	949-753-0001
Fax:	949-753-7412
E-mail:	tbuckley@linksmed.com

Contact Person:

Name	James Smith, Ph.D.
Address	29442 Pointe Royale Laguna Niguel, CA 92677
Telephone	949-340-7261
Fax:	949-340-7141
E-mail:	jrsmith00@cox.net

Date Prepared: March 10, 2014

Trade Name: MANUKA FILL
Common Name: Wound Dressing

Classification Name: Dressing, Wound, Drug

Device Class: Unclassified

Product Code: FRO

Predicate Devices: MANUKA FILL Wound Dressing (Links Medical Products, Inc.), BioAquaCare (BioArtificial Gel Technologies)

Predicate 510(k) #: K121227 (MANUKA FILL), K072068 (BioAquaCare)

Device Description: MANUKA FILL wound dressing is a sterile, single-use, wound care dressing that helps maintain a moist wound environment conducive to wound healing. The primary device consists of 100% *Leptospermum scoparium* honey from New Zealand sealed into low-density polyethylene (LDPE) tubes and sterilized using gamma irradiation.

Intended Use:

Under the supervision of a healthcare professional, MANUKA FILL wound dressing is indicated for the management of:

- Leg Ulcers
- Pressure Ulcers
- 1st and 2nd Degree Burns
- Diabetic Foot Ulcers
- Surgical Wounds
- Trauma Wounds

MANUKA FILL wound dressing provides a moist wound environment. A moist wound environment allows autolytic debridement of necrotic tissue.

Technology Comparison:

The technical characteristics of MANUKA FILL are substantially equivalent to the predicate devices. The wound dressings maintain a moist wound environment that promotes autolytic debridement conducive to wound healing. MANUKA FILL and its predicate (K121227) accomplish this by using 100% *Leptospermun socparium* honey as the primary ingredient, whereas BioAquaCare utilizes a hydrogel (95% water) to achieve the same goal. MANUKA FILL and its predicates are provided as single-use devices in individually sterilized packaging. Despite minor differences in materials, the devices are similar in function and intended use.

Nonclinical Testing:

Standard biocompatibility tests were performed on the MANUKA FILL wound dressing in accordance with ISO 10993-1 (Biological Evaluation of Medical Devices) and the FDA Biocompatibility Matrix, including cytotoxicity, skin irritation, and skin sensitization. In addition, a wound healing study was conducted to assess the impact of repeated application of MANUKA FILL to full-thickness dermal wounds in swine. The test articles did not impair healing and were determined to be as safe and effective as the predicate devices. All tests were performed by North American Science Associates (NAMSA). Additional testing included sterilization validation, shelf-life under accelerated and real-time conditions, and packaging validation. The MANUKA FILL wound dressing met the acceptance criteria for all tests conducted.

LINKS MEDICAL PRODUCTS, INC.
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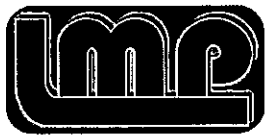
Irvine, CA 92618



Conclusion of Comparison: MANUKA FILL and its predicate devices were demonstrated to be biocompatible and met performance requirements for sterility, shelf life, and packaging. Based upon the technological characteristics and nonclinical performance data, MANUKA FILL wound dressings have been determined to be substantially equivalent and as safe and effective as its predicate devices (Manuka Fill and BioAquaCare).

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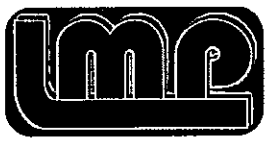

Intended Use:

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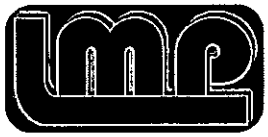

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 14, 2014

Links Medical Products Incorporated
James Smith, Ph.D.
Consultant
29442 Pointe Royale
Laguna Niguel, California 92677

Re: K131796
Trade/Device Name: MANUKA FILL
Regulatory Class: Unclassified
Product Code: FRO
Dated: February 14, 2014
Received: February 18, 2014

Dear Dr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K131796

Device Name: MANUKA FILL

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Prescription Use _____		Over-The-Counter Use: X
(Part 21 CFR 801 Subpart D)	AND/OR	(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jiyoung Dang -S

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Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use: ___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jiyoung Dang -S